

**[0016]** FIG. 4 is a process diagram of packaging a PAL kit according to one embodiment of the invention.

#### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

**[0017]** The present invention relates to sterile packaging of writing instruments, such as pens, for use in a medical environment. The sterile packaging may include labels packaged along with a pen in a pen and label (PAL) kit. The present invention also relates to methods of packaging a pen and/or the PAL kit. In particular, the method of packaging includes the steps of placing a writing instrument into packaging configured to be sealed such that the writing instrument is contained in a sealed portion of the packaging, sealing the package, and sterilizing the writing instrument and the package using gamma sterilization such that all portions of the writing instrument are sterilized.

**[0018]** In some embodiments, the packaging is an inner packaging, and the method further includes the steps of placing the sealed inner packaging into an outer packaging, placing at least one other item into the outer packaging, sealing the outer packaging such that the sealed inner packaging and the additional items are contained in a sealed portion of the outer packaging, and sterilizing using EtO sterilization such that the contents of the outer package are sterilized.

**[0019]** Some embodiments of the present invention relate to a kit including packaging, a writing instrument, and labels configured to be written on by a user with the writing instrument. In such embodiments, at least the writing instrument is sealed in the packaging, and at least the packaging and the writing instrument are sterilized using gamma sterilization.

**[0020]** In some embodiments, the packaging may be inner packaging, the kit further including outer packaging and at least one other item. In such embodiments, the outer packaging is sealed to include the sealed inner packaging containing the writing instrument, labels, and the at least one other item. The outer package contents are sterilized using EtO sterilization.

**[0021]** FIGS. 1A and 1B show a PAL kit 100 according to one embodiment of the present invention. The PAL kit 100 includes packaging 110, pen 120, and labels 130. Packaging 110 has a first layer 112 and a second layer 114 that may be sealed together at or adjacent to their respective peripheries. First layer 112 may be made of semi-permeable material such as Tyvek® or other gas-permeable material that would allow gasses to flow in and out without allowing contaminants to penetrate the material, maintaining the sterility of the interior and contents of PAL kit 100. The material of first layer 112 may also allow printing on the surface of first layer 112. Such printing may include, for example, identification and/or instructions. One example of such printing is shown in FIG. 1B.

**[0022]** Second layer 114 may be made of a gas and liquid impermeable transparent plastic material or any other suitable material. Second layer 114 may have a depression formed in the material to create a pocket or space for pen 120 and labels 130. Similarly a pocket may be formed in first layer 112. Alternatively, the pocket may be defined by neither layer, and may be implemented as a space defined between joined layers 112 and 114.

**[0023]** First layer 112 and second layer 114 of packaging 110 may be joined at a periphery to create a hermetically sealed interior pocket capable of holding contents such as pen 120, or labels 130, or both. Such packaging may be multivac

blister packaging. The layers 112 and 114 may be joined using any conventional joining processes including adhesives, welding, etc. In some embodiments, layers 112 and 114 may also be joined together to form more than one interior pocket allowing for production of several packages with continuous sheets of material, or allowing pen 120 and labels 130, or other objects, to be placed in separate pockets.

**[0024]** Layers 112 and 114 may also be joined such that on at least one side, the joined portion is located in from an edge of packaging 110 to enable a user to grasp the layers 112 and 114 individually and then separate the joined layers. In other embodiments, a periphery of packaging 110 may include a notch to allow the package to be easily torn open for use.

**[0025]** Pen 120 may be any conventional pen, such as a fine-tip, permanent ink pen. Pen 120 may be provided in a non-sterile initial state, prior to being placed and packaged in packaging 110 and sterilized. While pen 120 is illustrated in the Figures, any suitable writing instrument may be substituted for pen 120, such as a marker, pencil, electronic writing instrument, etc.

**[0026]** Labels 130 may be any labels that would accept and hold ink from pen 120, or otherwise lend themselves to being marked by a writing instrument. Labels 130 may include printing directed to the anticipated use of PAL kit 100. For example, as shown in FIG. 1A, at least one of labels 130 may be pre-printed with "HEP/SALINE" or other lettering such as "CONTRAST," "SALINE," "PREP SOLUTION," "LIDOCAINE," or any other printing. Similarly, labels 130 may be pre-printed with designated spaces for writing, such as spaces for date and initials to indicate when a product was prepared or administered, or when a sample was taken, and who completed the procedure. More generally, labels 130 may include any printed information that may be useful to a medical professional using a PAL kit.

**[0027]** In preparing PAL kit 100 as shown in FIGS. 1A and 1B, pen 120 and labels 130 are placed in packaging 110. Packaging 110 is then sealed to encapsulate pen 120 or labels 130, or both, in packaging 110. Packaging 110 may be hermetically sealed. After packaging 110 is sealed to include pen 120 or labels 130, or both, to create PAL kit 100, PAL kit 100 is sterilized using gamma sterilization. A printing process may also be performed to label PAL kit 100. The sealing and printing processes may be performed simultaneously to reduce production time.

**[0028]** Gamma sterilization requires a short cycle time, typically taking about one minute. PAL kit 100 is bombarded with gamma radiation, which penetrates through all materials in packaging 110, pen 120 and labels 130, sterilizing each component both internally and externally. As some materials are sensitive to gamma radiation, such that they become brittle and/or discolored, the materials selected for PAL kit 100 may be selected for their resistance to damage by gamma radiation. By using gamma sterilization, each portion of the PAL kit is sterilized, including all inside portions of pen 120, or other writing instrument, including the ink and inside of any lid or cap covering pen 120. Gamma sterilization also allows PAL kit 100 to be packaged without using a vacuum. This approach to packaging may limit manufacturing loss due to pen leakage and failure that can be caused by drawing a vacuum on pen 120. However, in some embodiments, vacuum packaged PAL kits may also be sterilized using gamma sterilization.

**[0029]** In FIG. 2, PAL kit 200 includes packaging 210 and pen 220. While labels may be included in PAL kit 200, PAL